PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Graham et al.
For:	A PATIENT VENTILATING AND ASPIRATING SYSTEM
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October 14, 2008
Date

Tiffany E. Lynch
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TRANSMITTAL OF CERTIFIED COPY
REGARDING CONVENTION CLAIM UNDER 35 U.S.C. §119

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In completion of Applicant's claim for priority under 35 U.S.C. §119 for United States Patent application, please find enclosed a certified copy of the corresponding New Zealand patent application as filed on 31 March 2004 with an application for Letters Patent number 532101.

It is believed that this completes Applicant's claim for priority, and acknowledgment of receipt of this priority document is requested.

Date: October 14 2008

Respectfully submitted,

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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 31 March 2004 with an application for Letters Patent number 532101 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 7 October 2008.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
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NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"Catheter Tube Connector"

We, FISHER & PAYKEL HEALTHCARE LIMITED a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a catheter tube connector, and in particular, but not solely to a catheter tube connector for a suction system used with a tracheostomy or endotracheal patient ventilation system.

Summary of the Prior Art

There are a number of medical procedures that require placement of a tracheostomy or endotracheal tube into the windpipe to deliver air directly into the lungs. A patient who is ventilated in this manner cannot clear secretions collecting in their lungs and airways by themselves. To overcome this problem, a sterile flexible aspirating tube is inserted into the patient via the tracheostomy or endotracheal tube. The aspirating tube is used in conjunction with an external vacuum source to create suction and help clear the secretions. In the method of secretion removal known as the open suction system, the aspirating tube is disposed of immediately after use as it will have become contaminated by the pathogens and bacteria that live in the patient's airway, and once it is removed from the patient's airway the tube will be exposed to atmosphere, with the risk of contaminating caregivers. An alternative to the open suction system is known as the closed suction system, where the aspirating tube is enclosed within a sealed flexible plastic envelope when outside the patient, allowing the aspirating tube to be used several times and then changed either when necessary or after a set period, usually every 24 hours. The closed suction system provides a degree of protection from contaminants for anyone in contact with the patient, such as caregivers and similarly protects the patient from caregivers and the like. Since it was first introduced, various aspects of the closed system have been refined in order to improve the usefulness of the system.

US 4,351,328 discloses a combined tracheostomy ventilator tube and patient aspirating system of the open type. The device disclosed has the disadvantage that the aspirating catheter tube is exposed to the atmosphere before being pushed into the trachea via the tracheostomy tube. The catheter tube also comes into contact with the external parts of the seal as it penetrates through it, allowing it to pick up germs on the external surfaces of the ventilator before depositing these in the patient's lungs. A further disadvantage of this system is that the resistance of the tube passing through and over the seal can be high, and can cause the patient some discomfort as the

tracheostomy tube and other fittings are inadvertently moved and twisted in order to overcome this resistance.

US 4,569,344 discloses a combined tracheostomy ventilator tube and patient aspirating system of the closed type. The device disclosed has the disadvantage that the ventilator tube is unsealed when the connector is released in order to carry out routine cleaning or maintenance, or in order to replace the aspirating system, allowing external airborne germs to enter the trachea through the ventilator tube. Also, it is difficult to maintain PEEP (Positive end-expiratory pressure) within the system if the system is not sealed, such as is the case here when the connector is released. If PEEP is not maintained throughout the system, not only can this affect the ventilation of the patient, but in the most common form of tracheal tube layout, an inflated cuff is used to hold and seal the ventilation and aspiration cannula of the tracheostomy tube in place in the patient's windpipe. If PEEP is lost, this cuff can deflate, allowing subglottic fluids that have pooled above the cuff to leak into the patient's lungs. The device disclosed in this specification also has the disadvantage that the end of the catheter tube is fully exposed before connection, and makes contact with exposed portions of the external surfaces of the ventilator as it is pushed through into the trachea, leading to a greater chance of infecting the patient.

US 5,060,646 discloses a similar closed system for ventilation and aspiration. This system has the disadvantage that the aspirating assembly containing the catheter tube cannot be removed for replacement or maintenance without unsealing the ventilating system, making it difficult to maintain PEEP, and allowing airborne germs to enter the system. Whilst in this case the catheter tube can be inserted into the ventilator without coming into contact with the external surfaces, this can only occur when the ventilator is unsealed, with the previously mentioned disadvantages. Also, removing and connecting the aspirating assembly is via a resistance fitting, and so the patient can experience discomfort from the increased likelihood of twisting and pulling, as outlined above.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a ventilating and aspirating apparatus that overcomes one or more of the abovementioned problems or disadvantages, or which at least provides the public with a useful alternative.

In a first aspect the invention may broadly be said to consist in a patient ventilating and aspirating system, comprising:

a pressurised source of gases,

gases transport means adapted to convey said gases in use to said patient,

a patient connector, adapted to deliver said gases to a patient through a tracheostomy or endotracheal tube fitting, said patient connector adapted to be in fluid communication with said gases transport means in use,

a catheter mount, including an elbow connector, adapted to be fitted in use to said patient connector and to be used as part of said gases transport means, said catheter mount containing a passage passing between the inside and the outside of said gases transport means, said passage closed by a sealing means, said sealing means having a re-sealing mechanism, allowing the passage to be re-closed once the seal formed by said sealing means has been broken,

a suction catheter tube, with a distal end and a proximal end, said suction catheter tube surrounded by a sealed collapsible envelope, the ends of said suction catheter tube fitted with a distal connector and moveable through a proximal connector respectively, said distal connector adapted to allow said distal end of said suction catheter tube to be connected to a suction means in use, said proximal connector adapted to allow releasable connection to said passage in said catheter mount, said proximal connector further adapted so that all or a portion of said suction catheter tube may be passed through said proximal connector in use, said proximal connector yet still further adapted to pierce said sealing means in such a manner that the proximal end of said catheter tube can pass through said passage and enter and exit said gases transport means without contacting the external surfaces of said suction catheter mount or said sealing means.

Preferably said proximal connector is adapted such that when connected to said catheter mount a chamber is formed, said chamber surrounding the outside part of said sealing means and creates a dead space, said proximal connector and said catheter mount adapted such that when connected, adjacent surfaces on said proximal connector and said catheter mount will abut to form a seal and prevent gases which leak into said chamber through said sealing means from exiting to the atmosphere.

Preferably said releasable connection is a bayonet fitting.

Preferably said sealing means is made from an elastomeric material, and provides a substantially airtight seal at normal operating pressures, said sealing means having a perforation in said elastomeric material, said perforation allowing said proximal connector to pierce said sealing means and further allowing said elastomeric

material to re-seal said passageway once said proximal connector is detached from said catheter mount.

Preferably said chamber and said dead space are shaped in such a manner that gases within said gases transport means that leak through said sealing means once pierced are enclosed and contained within said dead space.

Preferably said passageway is located on said catheter mount in such a manner that when said suction catheter tube is pushed through into said catheter mount in use, said suction catheter tube can enter said tracheostomy or endotracheal fitting without contacting the internal walls of any of said catheter mount or said gases transport means.

In a second aspect the invention may broadly be said to consist in a suction catheter tube and connector comprising:

a suction catheter tube, with a distal end and a proximal end, said suction catheter tube surrounded by a sealed collapsible envelope, the ends of said suction catheter tube fitted with a distal connector and moveable through a proximal connector respectively, said distal connector adapted to allow said distal end of said suction catheter tube to be connected to a suction means in use, said proximal connector adapted to allow releasable connection to said passage in said catheter mount, said proximal connector further adapted so that all or a portion of said suction catheter tube may be passed through said proximal connector in use, said proximal connector yet still further adapted to pierce a seal upon connection to a ventilating device.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

While the invention may be susceptible to embodiment in different forms, one specific embodiment is shown in the drawings, and described in detail. The present disclosure is to be considered an exemplification of the principles of the invention, and is not intended to limit the invention to that as illustrated and described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred form of the present invention will now be described with reference to the accompanying drawings.

Figure 1 shows a ventilating circuit in use by a patient, such as might be used with the present invention, in particular an aspirating assembly of the present invention is shown utilising an elbow connector, catheter mount and a tracheostomy or endotracheal connector.

Figure 2 is a detailed view of the aspirating assembly and the catheter mount and elbow connector of Figure 1, showing also the patient and a ventilation tube that connects the aspirating assembly to a suction pump.

Figure 3 is a detailed view of the aspirating assembly, showing the catheter mount and elbow connector disconnected from the aspirating assembly.

Figure 4 is a further detailed view of the catheter mount and elbow connector that has an elastomeric seal with a perforation, and a bayonet fitting for connecting the two.

Figure 5 is a detail cutaway view of the proximal end connector attached to the catheter mount, showing a dead space being created when the aspirating assembly is attached to the catheter mount, and the catheter tube passing through the central protrusion and the seal, and into the catheter mount.

Figure 6 shows an alternative embodiment of the catheter mount of the present invention, where a bifurcated y-shaped tracheostomy connector is used in place of the catheter mount and tracheostomy connector.

Figure 7 shows a further alternative embodiment of the catheter mount of the present invention, with a cross- or x-shaped fitting used in place of the T-shaped fitting of the preferred embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention consists of several separate pieces that are fitted together to form a system to ventilate and aspirate a patient 3. Firstly the system comprises a tracheostomy or endotracheal connector 1 (hereinafter "patient connector 1") which in use attaches to the tracheostomy or endotracheal fitting 2 located in the neck or throat of a patient 3. In the Figures the patient is only shown with tracheostomy not an endotracheal fitting and tube. Secondly, an elbow connector 6 attached to the patient connector 1 is provided. Thirdly a catheter mount 4 is attached to the elbow connector 6 and lastly, an aspirating assembly 8, which is attached to the

elbow connector 6. Note should be made that the catheter mount 4 is effectively a piece of tubing that connects the elbow connector 6 to the ventilator system.

In the preferred embodiment described, the patient has undergone surgery and has had a tracheostomy or endotracheal fitting 2 inserted into his or her tracheostomy in order to allow ventilation and aspiration.

Referring to Figures 1 and 2, a ventilation and humidifying circuit as might be used with the suction catheter tube connector of the present invention is shown. A patient 3 is receiving humidified and pressurised gases through the tracheostomy or endotracheal fitting 2 (hereinafter "patient fitting 2"). The catheter mount 4 is connected to a humidified gases transportation pathway or inspiratory conduit 7 that in turn is connected to a humidifier 25 supplied with gases from a ventilator 23. An expiratory conduit 24 transports gases from the patient back into the ventilator to assist the breathing of patient 3. The ventilator 23, humidifier 25 and conduit 24 that makes up the ventilation and humidifying circuit have all been well described in the prior art, and may be of the type described in US 5,640,951 to Fisher and Paykel Limited.

The aspirating assembly 8 consists of a suction catheter tube 9, a collapsible and flexible plastic envelope 10 and at least two fittings at each end, in particular, a distal fitting 11 furthest from the patient, and a proximal fitting 12 nearest to the patient 3. The suction catheter tube 9 is capable of being slid backwards and forwards through the proximal fitting 12, such that in use the envelope 10 collapses and expands back out lengthwise with movement of the suction catheter tube 9. The proximal fitting 12 has a releasable connector mechanism allowing attachment to the elbow connector 6 and hence catheter mount 4. The plastic envelope 10 contains any hazardous biological waste from the lungs of the patient 3 that may be deposited on the outside of the catheter tube 9. The distal fitting 11 is connected to a suction pump 13. The suction from pump 13 is used to suck fluid from the lungs and airways passages of the patient 3 through the suction catheter tube 9.

In order for the suction catheter tube 9 to access the lungs and airways of the patient 3, its length can be pushed through the proximal fitting 12, passing through the elbow connector 6, the patient connector 1 and the patient fitting 2 and then into the lungs of the patient 3. In order to prevent obstruction of the patient's airways the suction catheter tube 9 is not left inside the patient 3 when not in use. Thus the

suction catheter tube 9 is substantially completely withdrawn back through the proximal fitting 12 and into the plastic envelope 10 when not in use.

The proximal fitting 12 releasably connects the aspirating assembly 8 to the elbow connector 6. In the preferred embodiment shown in Figures 3 and 4, the elbow connector 6 and catheter mount 4 is substantially T-shaped in cross-section. The upright of the T-section forms or is connected to the ventilation tube 4. The end of the arm of the T-section forms or is connected to the patient connector 1 and the other end forms a passage 15 which receives the proximal connector 12 of the aspirating assembly 8. A seal 16 is located at the outermost end of passage 15 and seals passage 15. In the preferred embodiment this is an elastomeric material, such as a silicone rubber, and has a slit 17 formed in the centre of the seal. The slit 17 allows the seal 16 to be pierced, for example by a central protrusion 20 (described below) or the suction catheter tube 9, but then to reseal once the object piercing the seal has been removed.

In other forms of the elbow connector and catheter mount an L-shaped configuration may exist where the corner of the L has located within it an aperture in which an elastomeric seal, very similar to above. In this configuration the passage 15 would be shorter in length.

Referring now to Figure 5, the proximal fitting 12 consists of two nested cup-shaped fittings, an inner cup fitting 18 and an outer cup fitting 19, extending around a central protrusion 20. The central protrusion 20 preferably projects past the rim 28 of the outer cup fitting 19, although it is not strictly necessary that the protrusion 20 does. The rim 28 of the outer cup fitting 19 projects past the rim 27 of the inner cup fitting 18. The outer cup fitting 19 preferably has an internal diameter slightly larger than the outer diameter of the elbow connector 6 that forms the passage 15. The inner cup fitting 18 has a diameter slightly smaller than the outer diameter of the cross-piece of the catheter mount 6. The proximal fitting 12 and the elbow connector 6 are brought together and connected so that the central protrusion 20 passes through the slit 17 in elastomeric seal 16, and protrudes into the passage 15. The rim of the inner cup fitting 18 abuts the end of the passage 15. A dead space 21 is formed between the outside surface of the seal 16, the inside of the inner cup fitting 18 and the outside surface of the protrusion 20. It is not considered necessary for the seal 16 to be airtight and stop gases escaping to atmosphere when the elbow connector 6 and the aspirating assembly 8 are connected in this manner, as sealing occurs between the seal 16 and the end 27 of the inner cup fitting 18. In any event, any possible leakage that

may occur is contained in the dead space 21 formed on connection. The dead space 21 breaks the direct path between gases flowing through the seal 16 and atmosphere as the elbow connector 6 and aspirating assembly 8 are brought together. Once the rim 27 of the inner cup fitting 18 has been pushed against the seal 16 at the end of the passage 15, the rim 27 of the inner cup fitting 18 and seal 16 form a seal that prevents any further leakage to atmosphere.

As the inner cup fitting 18 abuts the seal 16, part of the outer cup fitting 19 overlaps and wraps around the outer end portion 29 of the passage 15. The passage 15 and the outer cup fitting 19 are fitted with a releasable lockable bayonet fitting 22 of the type well known in the prior art. The bayonet fitting 22 prevents inadvertent release of the proximal connector 12 from the elbow connector 6.

In the preferred embodiment, the central protrusion 20 is a hollow tube protruding from the proximal fitting 12. The catheter tube 9 fits snugly within the central protrusion 20, and slides easily within it. This snug fit has the advantage that little or no gases escape through the seal 16 to pass between the catheter tube 9 and the central protrusion 20. In the event that gases did escape an additional seal 30 within the proximal fitting 12 prevents gases entering the envelope 10.

In some forms of the present invention the envelope 10 may be formed of a breathable material, such as SYMPATEX™.

In use, when the proximal fitting 12 and the elbow connector 6 are mated, the protrusion 20 is pushed through the slit 17 in the seal 16 and the proximal connector 12 is locked to the catheter mount 6 using the bayonet fitting 22. The end of the suction catheter tube 9 may then be pushed through the hollow centre of the central protrusion 20 into the elbow connector 6 and then on through into the patient connector 1, the patient fitting 2 and into the lungs of the patient 3. After suction operations have been completed, the suction catheter tube 9 may be withdrawn back through the proximal connector 12 and any contaminants on the outside surface of the suction catheter tube 9 are contained safely within the plastic envelope 10.

Once the aspirating assembly 8 and the elbow connector 6 have been mated, there is little or no inadvertent forcing or twisting of the elbow connector and catheter mount in order to push the suction catheter tube 9 through the seal 16, and suction catheter tube 9 moves easily within the tube formed by the central protrusion 20. There is therefore a decrease degree of patient trauma offered by the system of the present invention. The seal 16 and the features of the proximal connector 12 outlined

above also ensure that any gas leakage through the seal 16 does not result in an excessive loss of PEEP.

In the preferred embodiment of the present invention described and shown in the figures, the patient connector 1 is connected to, or can be an integral part of, the elbow connector 6. This is a common embodiment for ventilation circuits of this type, although bifurcated y-shaped tracheostomy fittings 5 of the type shown in Figure 6 that allow an elbow connector 6 and a catheter mount 4 to be separately connected are not unknown.

A similar alternative system is shown in Figure 7 where the aspirating assembly 8 is attached to a cross- or x-shaped catheter mount 26. One branch of the catheter mount 26 forms the passage 15 and the opposing branch forms the patient connector 2. In this embodiment one of the side branches forms the inspiratory conduit 7 and the opposed branch forms either a bleed-off exhalation conduit or expiratory conduit 24 leading back to the ventilator 23 (if being used in an assisted breathing configuration).

Systems of both the types described above in the preferred embodiment and the alternative forms with the bifurcated y-shaped tracheostomy fitting 5, or the x-shaped catheter mount 26, have the advantage that they are modular, and the separate parts, such as the elbow connector 6 or the aspirating assembly, 8 can be easily removed from the system and replaced if necessary. This is especially useful as the aspirating assembly 8 will likely need to be removed and replaced much more frequently that the other parts.

DATED THIS 31st DAY OF March 2004
AJ PARK
PER
AGENTS FOR THE APPLICANT

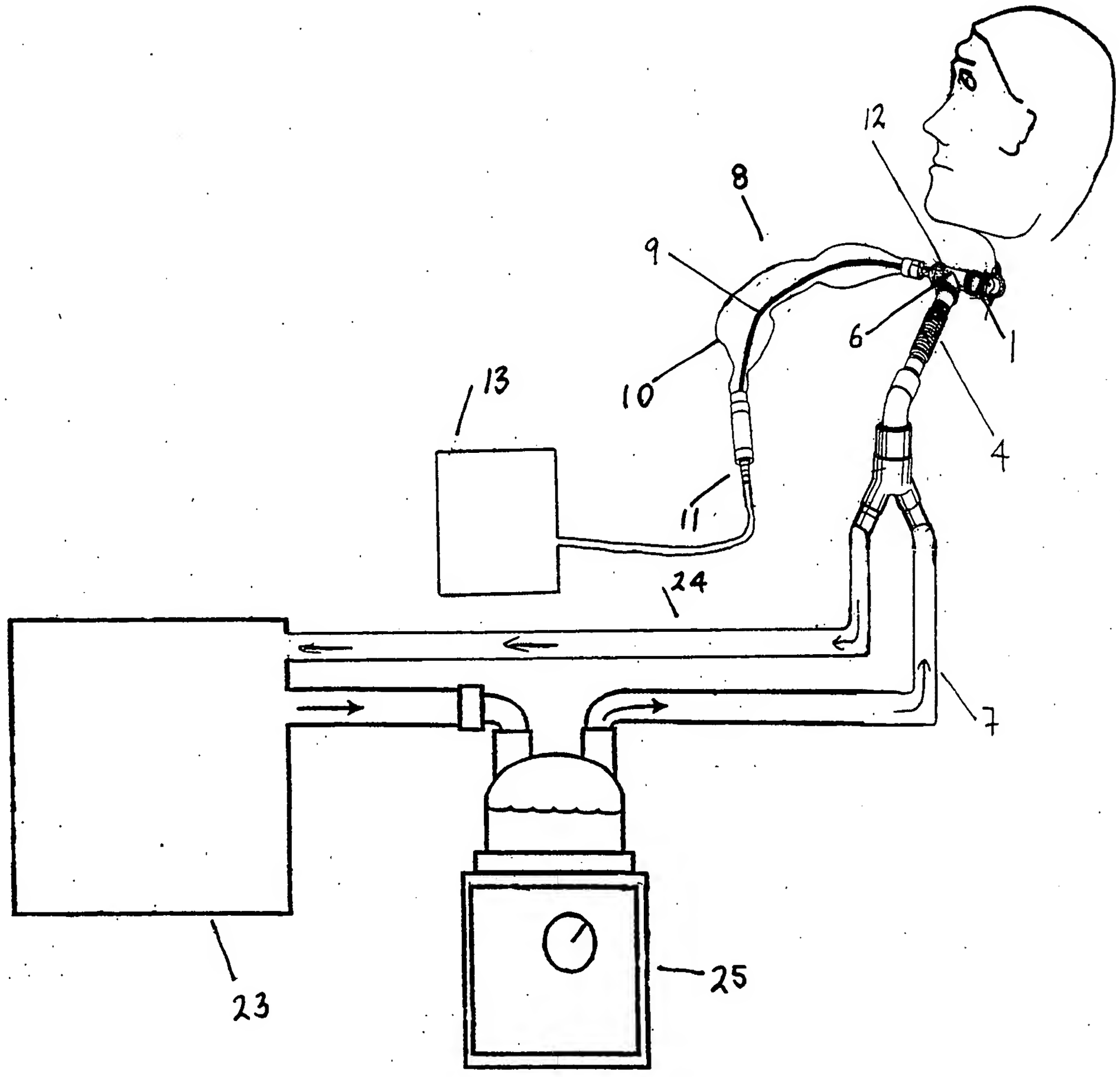

Figure 1

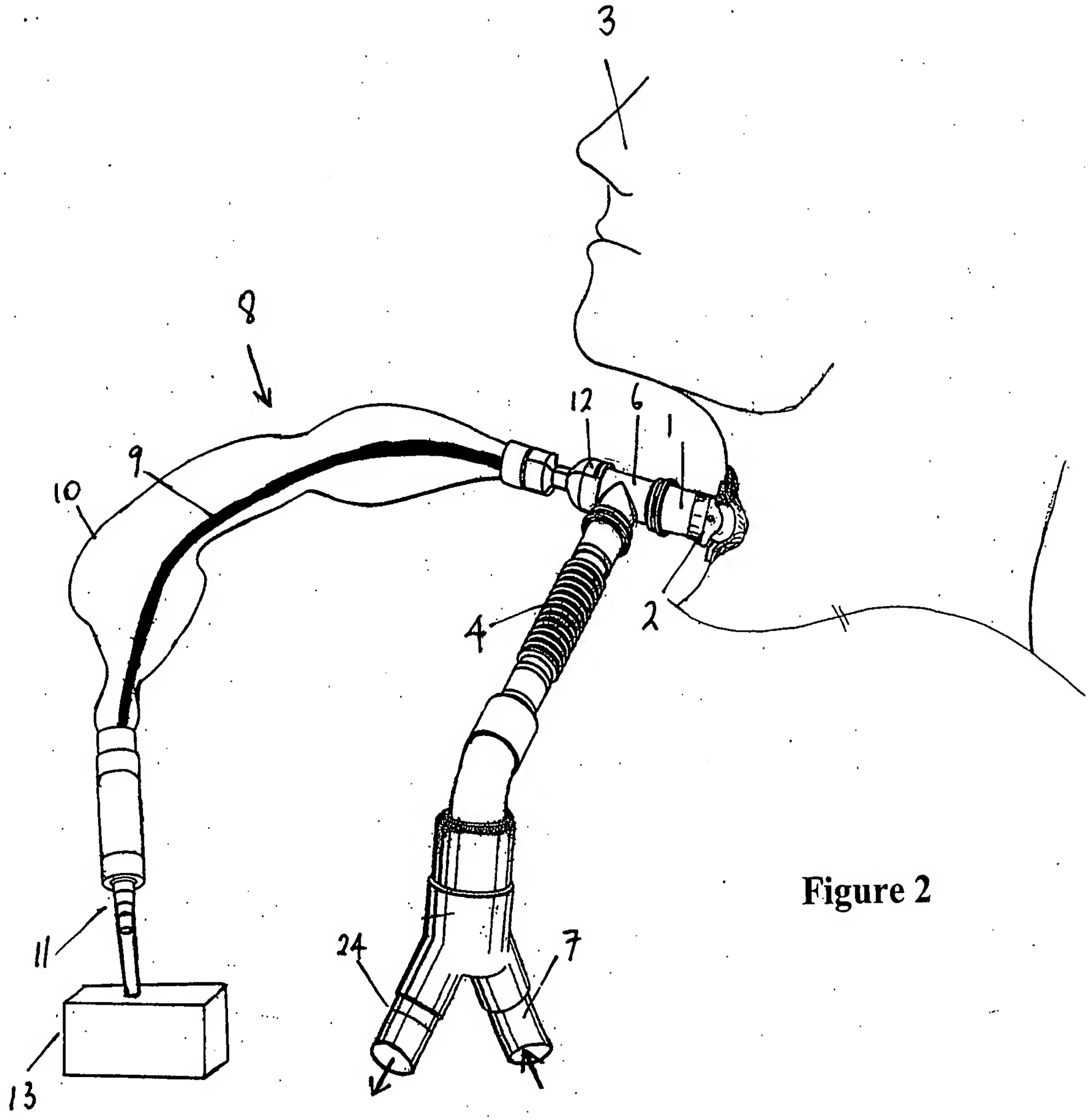

Figure 2

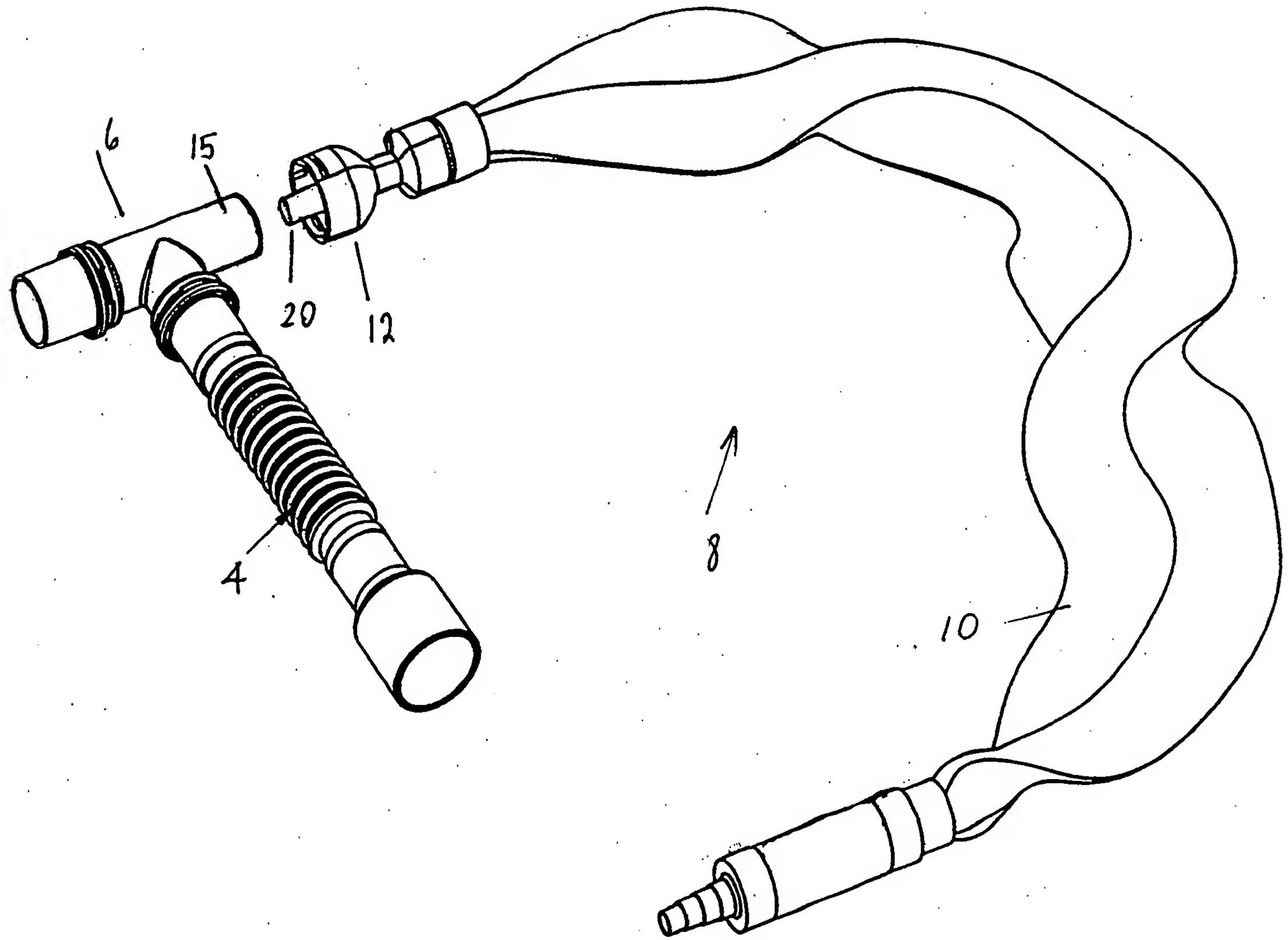

Figure 3

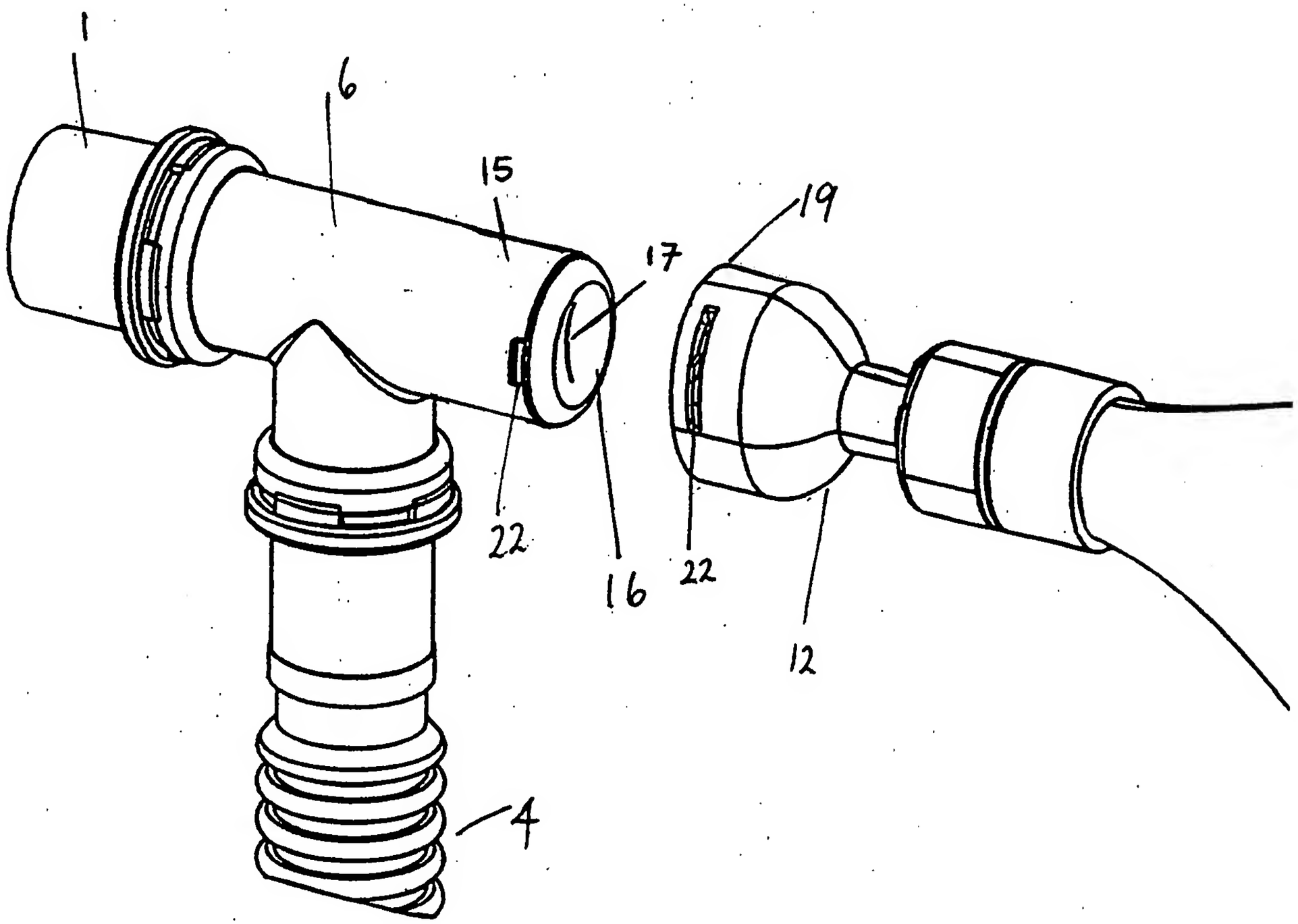

Figure 4

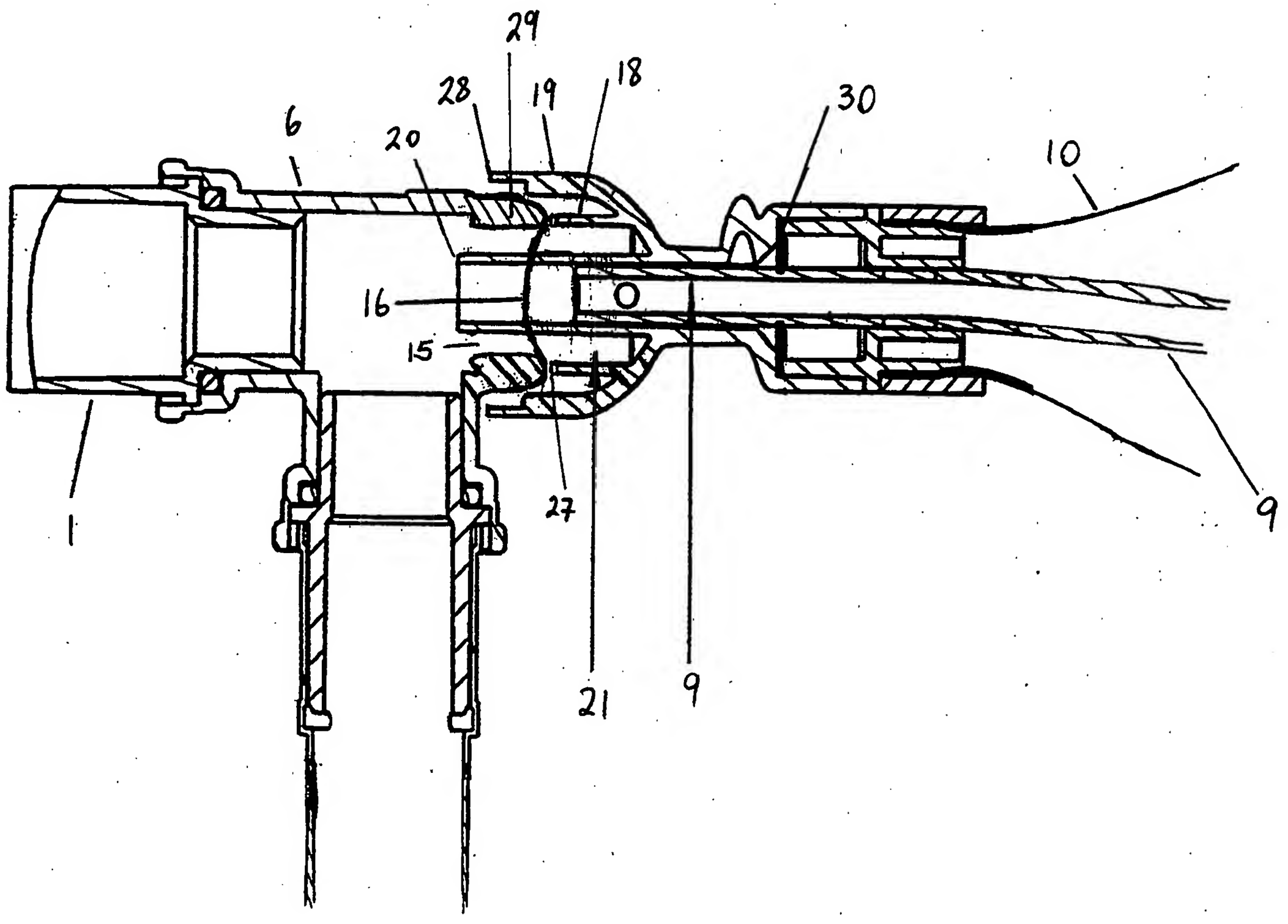

Figure 5

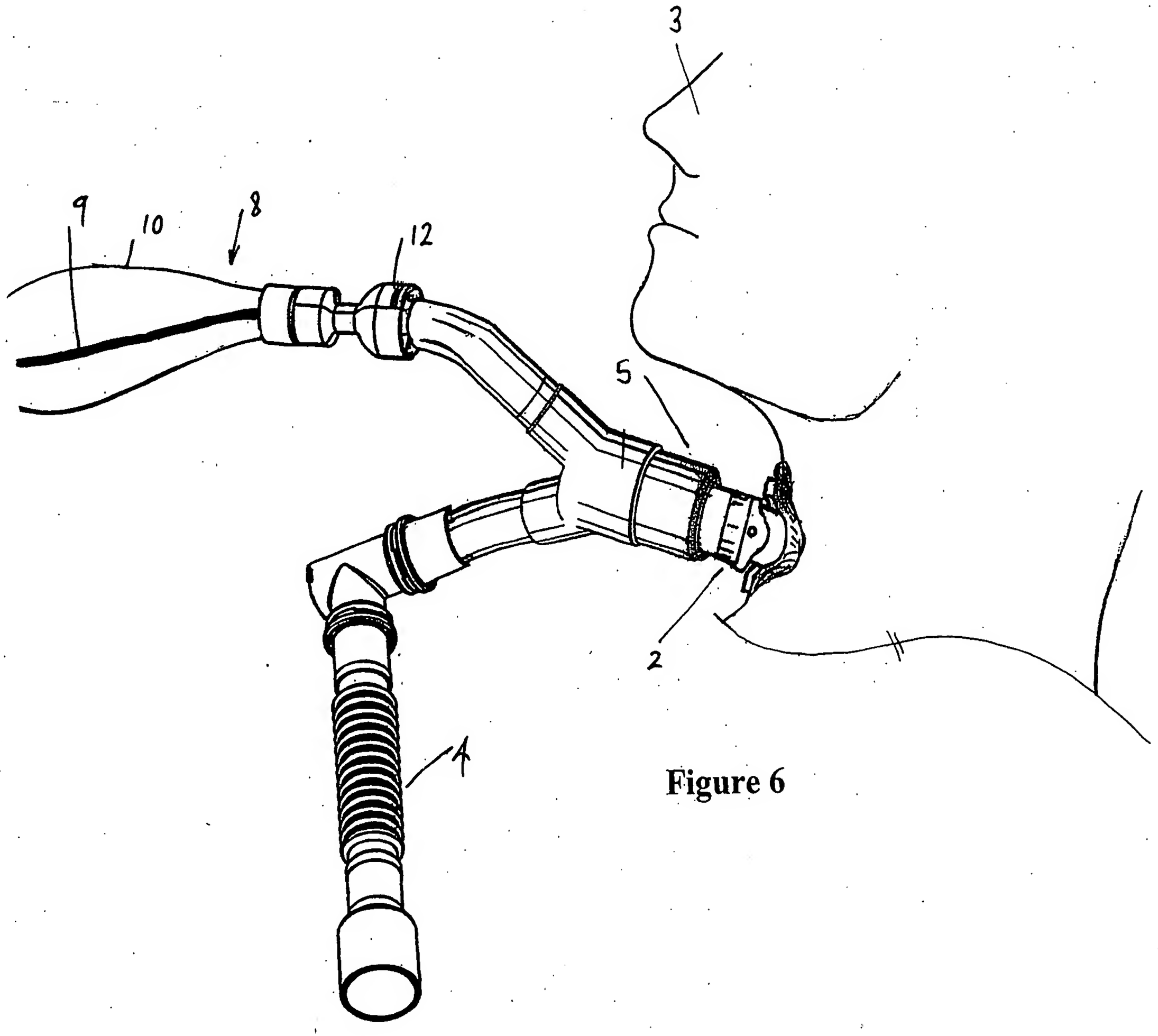

Figure 6

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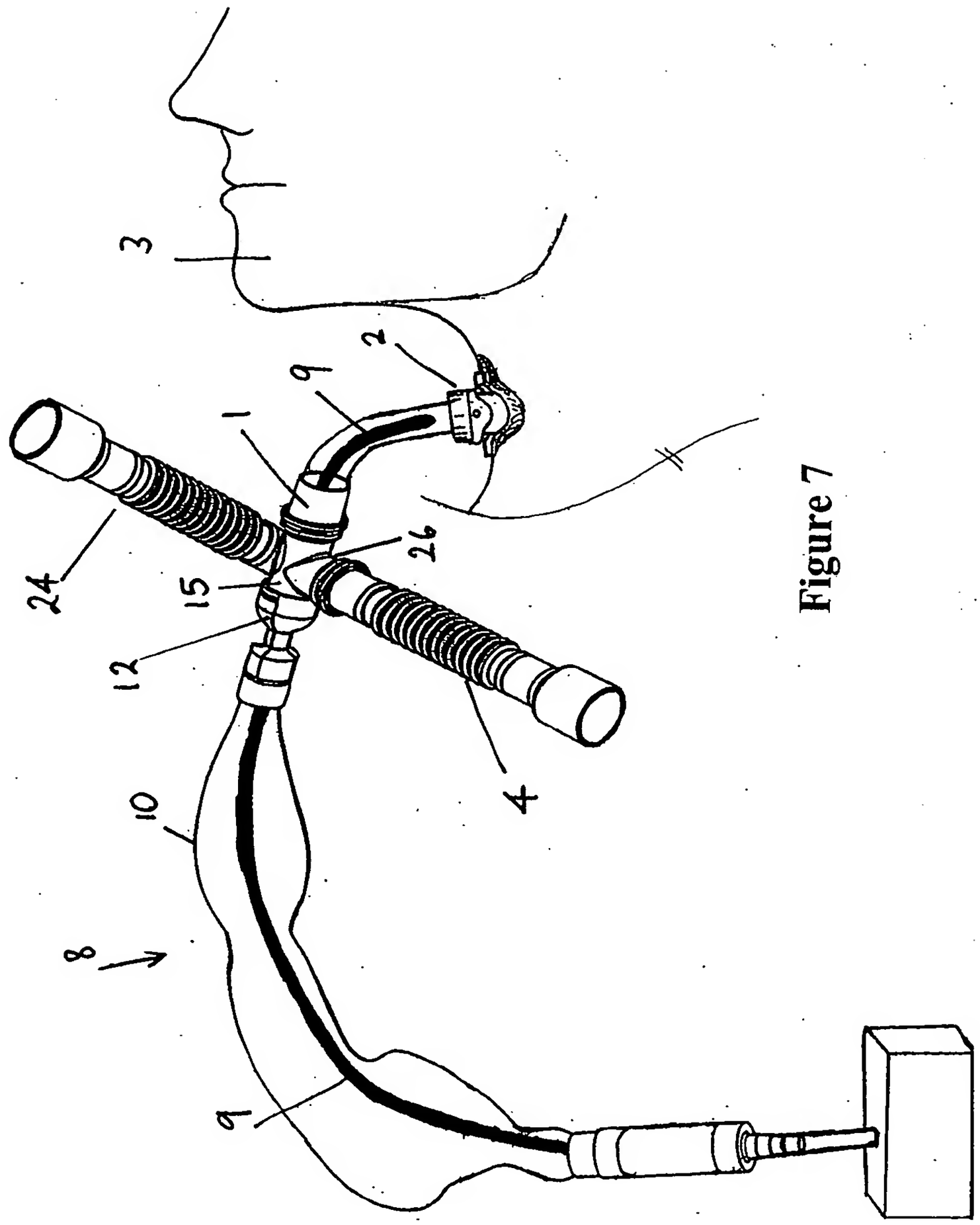

Figure 7